Cahoy Dec. Ex. 64

From: Glenn P
Sent: Wednesday, May 25, 2022 3:56 PM PDT
To: Skodacek, Ken; Chris G
Subject: Re: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

Ken.
Thanks for the follow-up. Chris and I are available after 10:00 AM tomorrow. We'd be happy to speak with you, just send an invite.
Glenn
Glenn Papit
Vice President
Rebotix Repair
407-810-4176
https://www.rebotixrepair.com
From: Skodacek, Ken <Ken.Skodacek@fda.hhs.gov>
Sent: Wednesday, May 25, 2022 3:44 PM
To: Chris G <chris@rebotixrepair.com>; Glenn P <glennpapit@rebotixrepair.com>
Cc: CDRH Ombudsman <CDRHOmbudsman@fda.hhs.gov>
Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

Chris and Glenn – As you requested, I discussed your proposed plan with some members of the FDA team. Could we have a brief conversation tomorrow, Thursday? What is your availability? I would like to review and confirm the next steps before sharing the plan with a larger group.

Regards,
Ken
Ken Skodacek (he/him)
CDRH Deputy Ombudsman

From: Skodacek, Ken
Sent: Thursday, May 19, 2022 11:27 PM
To: Chris G <chris@rebotixrepair.com>; Bittleman, Katelyn <Katelyn.Bittleman@fda.hhs.gov>; Lee, Anthony <Anthony.Lee1@fda.hhs.gov>
Cc: Rick Lyon <rick@dovel.com>; Glenn P <glennpapit@rebotixrepair.com>; Trumbore, Mark <Mark.Trumbore@fda.hhs.gov>; CDRH Ombudsman <CDRHOmbudsman@fda.hhs.gov>
Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

OK, great. I sent you an invite for Monday at 9:30 AM ET. I've copied the staff from CDRH on this message, but we can meet privately, so that you're able to have a confidential discussion with me about your questions.

Exhibit
DX 267

Ken Skodacek (he/him)
CDRH Deputy Ombudsman

From: Chris G <chris@rebotixrepair.com>
Sent: Thursday, May 19, 2022 9:26 AM
To: Skodacek, Ken <Ken.Skodacek@fda.hhs.gov>; Bittleman, Katelyn <Katelyn.Bittleman@fda.hhs.gov>; Lee, Anthony <Anthony.Lee1@fda.hhs.gov>
Cc: Rick Lyon <rick@dovel.com>; Glenn P <glennpapit@rebotixrepair.com>; Trumbore, Mark <Mark.Trumbore@fda.hhs.gov>; CDRH Ombudsman <CDRHOmbudsman@fda.hhs.gov>
Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

Good morning Ken,
Thank you for the quick response on this matter. We can be available Monday, Thursday, or Friday next week.

Please let me know if any of these dates work for you. Thank you.

Sincerely,

Chris Gibson
Chief Operations Officer
Rebotix™
your prescription for savings
539 Pasadena Avenue South
St. Petersburg, FL 33707
P: (727) 345-6362
F: (727) 343-4637
C: (813) 245-3974
www.rebotixrepair.com

From: Skodacek, Ken <Ken.Skodacek@fda.hhs.gov>
Sent: Wednesday, May 18, 2022 7:35 AM

To: Bittleman, Katelyn <Katelyn.Bittleman@fda.hhs.gov>; Chris G <chris@rebotixrepair.com>; Lee, Anthony <Anthony.Lee1@fda.hhs.gov>
Cc: Rick Lyon <rick@dovel.com>; Glenn P <glennpapit@rebotixrepair.com>; Trumbore, Mark <Mark.Trumbore@fda.hhs.gov>; CDRH Ombudsman <CDRHOmbudsman@fda.hhs.gov>
Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

Thank you, Katelyn, for the introduction. **Chris** – Please let me know your availability this week to discuss any questions that you might have. Once I hear back from you, I can send you an invitation for a date/time that works for our mutual schedules.

Ken Skodacek (he/him)
CDRH Deputy Ombudsman
Center for Devices and Radiological Health
Office of Policy
U.S. Food and Drug Administration
Tel: 301-796-6364
Ken.Skodacek@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide your feedback.

From: Bittleman, Katelyn <Katelyn.Bittleman@fda.hhs.gov>
Sent: Tuesday, May 17, 2022 6:24 PM
To: Chris G <chris@rebotixrepair.com>; Lee, Anthony <Anthony.Lee1@fda.hhs.gov>
Cc: Rick Lyon <rick@dovel.com>; Glenn P <glennpapit@rebotixrepair.com>; Trumbore, Mark <Mark.Trumbore@fda.hhs.gov>; Skodacek, Ken <Ken.Skodacek@fda.hhs.gov>
Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

Hi Chris,

Thanks for reaching out. To clarify about escalation, we have not taken a regulatory or enforcement action at this time for the formal appeals process to apply. As stated on the call, we do believe the activities you are performing constitute remanufacturing and require premarket review. As noted in the guidance documents listed below, this is not considered a "significant decision." However, you are welcome to escalate the discussion and decision with the next level supervisor. In this case that would most likely be Dr. Cynthia Long, Division Director of General Surgery Devices. After Dr. Long, the next level supervisor would be Dr. Binita Ashar, Director of the Office of Surgery and Infection Control Devices.

The CDRH Deputy Ombudsman, Ken Skodacek, was on our last call and is familiar with the situation. He would be happy to answer any additional questions you may have on the process. Additionally, these two guidance documents are related to appeals; I encourage you to review them if you have not already.

1. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/center-devices-and-radiological-health-cdrh-appeals-processes
2. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/center-devices-and-radiological-health-cdrh-appeals-processes-questions-and-answers-about-517a.

I hope this answers your questions. Thanks again for reaching out.

-Katelyn

Katelyn R. Bittleman, Ph.D. (she/her/hers)
Policy Analyst, Compliance and Quality Staff

Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 4250 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (240) 402-1478
Katelyn.Bittleman@fda.hhs.gov

From: Chris G <chris@rebotixrepair.com>
Sent: Tuesday, May 17, 2022 11:16 AM
To: Lee, Anthony <Anthony.Lee1@fda.hhs.gov>
Cc: Rick Lyon <rick@dovel.com>; Glenn P <glennpapit@rebotixrepair.com>; Bittleman, Katelyn <Katelyn.Bittleman@fda.hhs.gov>; Trumbore, Mark <Mark.Trumbore@fda.hhs.gov>
Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

Dear Dr. Lee and FDA Team:

Thank you for taking the time to speak with us. We certainly want to continue working with the FDA to resolve this matter, but we were hoping you could clarify something for us. Based on your emails of April 6th and 8th and zoom meeting of April 8th, we understood that the FDA had made a "decision" classifying Rebotix activities as remanufacture. We further understood that we had the right to appeal this decision for supervisory review under 21 CFR 10.75. During the May 11th zoom, someone (Dr. Bittleman I believe) specifically referenced supervisory review under 21 CFR 10.75 as an option. But then later during the May 11th zoom, someone else (Dr. Trombore I believe) stated that "no formal decision had been made" and there was "nothing for [us] to appeal" at this point. We are a bit confused by this apparent contradiction and how it affects next steps. Can you please clarify. When you indicate below that we have the option to "escalate to a higher level for additional discussion," are you referring to supervisory review under 21 CFR 10.75 or some other process? Also, at some point, would it be acceptable for Rebotix to reach out to the FDA Omsbudsman?

Thank you again for your time.

Sincerely,

Chris Gibson
Chief Operations Officer
Rebotix™
your prescription for savings
539 Pasadena Avenue South
St. Petersburg, FL 33707
P: (727) 345-6362
F: (727) 343-4637
C: (813) 245-3974
www.rebotixrepair.com

From: Lee, Anthony <Anthony.Lee1@fda.hhs.gov>
Sent: Friday, May 13, 2022 2:59 PM
To: Chris G <chris@rebotixrepair.com>
Cc: Rick Lyon <rick@dovel.com>; Glenn P <glennpapit@rebotixrepair.com>
Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

Dear Mr. Gibson and Rebotix team,
Thank you again for having the call with us on Wednesday. From our understanding, you will let me know how you intend to proceed within the next two weeks. Those options being:

1. Requesting to escalate to a higher level for additional discussion,
2. Committing to a premarket submission, or
3. Stating that you will no longer be marketing this activity.

In addition, it was suggested that other firms are engaged in this space without the same level and breadth of quality checks and testing that your team uses. If you can share additional information about those companies, we would very much be interested in learning about them. I look forward to hearing back from you.

Best regards,
Anthony Lee

Anthony Lee, PhD, MBA
Team Lead

Robotic Assisted Surgery Devices Team
Division of Health Technology 4A | OHT4: Surgical & Infection Control Devices
Office of Product Evaluation and Quality | Center for Devices and Radiological Health

Office: (240) 402-5935
E-mail: Anthony.Lee1@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1611&S=E

From: Lee, Anthony
Sent: Thursday, May 5, 2022 4:39 PM
To: Chris G <chris@rebotixrepair.com>; Bittleman, Katelyn <Katelyn.Bittleman@fda.hhs.gov>
Cc: Rick Lyon <rick@dovel.com>; Glenn P <glennpapit@rebotixrepair.com>
Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

Hi Mr. Gibson,
We have availability next week as follows:

Wednesday, 5/11 at 4PM EDT
Thursday, 5/12 at 4:30PM EDT

If neither of these work, please let me know and we will check additional options for Friday and beyond.

Regarding your question, I don't have an immediate answer to that, but we will be able to discuss any process questions you may have during the meeting.

Thank you,
Anthony Lee

Anthony Lee, PhD, MBA
Team Lead

Robotic Assisted Surgery Devices Team
Division of Health Technology 4A | OHT4: Surgical & Infection Control Devices
Office of Product Evaluation and Quality | Center for Devices and Radiological Health

Office: (240) 402-5935
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https://www.research.net/s/cdrhcustomerservice?ID=1611&S=E

From: Chris G <chris@rebotixrepair.com>
Sent: Thursday, May 5, 2022 9:13 AM
To: Lee, Anthony <Anthony.Lee1@fda.hhs.gov>; Bittleman, Katelyn <Katelyn.Bittleman@fda.hhs.gov>
Cc: Rick Lyon <rick@dovel.com>; Glenn P <glennpapit@rebotixrepair.com>
Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

Dear Dr. Lee,

We are available next Tuesday, Wednesday or Thursday as you request. Please send potential times available for you and your team to attend the Zoom call. Also, we assume that the date to file an appeal will be extended due to your requested delay. Please confirm. Thank you.

Sincerely,

Chris Gibson
Chief Operations Officer
Rebotix™ your prescription for savings
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St. Petersburg, FL 33707
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F: (727) 343-4637
C: (813) 245-3974
www.rebotixrepair.com

From: Lee, Anthony <Anthony.Lee1@fda.hhs.gov>
Sent: Wednesday, May 4, 2022 5:11 PM
To: Chris G <chris@rebotixrepair.com>; Bittleman, Katelyn <Katelyn.Bittleman@fda.hhs.gov>
Cc: Rick Lyon <rick@dovel.com>; Glenn P <glennpapit@rebotixrepair.com>
Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

Dear Mr. Gibson,
Apologies for causing a delay, but we have run into a scheduling conflict for this Friday's time slot and need to reschedule the call. It would only be a few days, as we are trying our best to honor your request for a meeting as soon as possible. We are currently trying to find availability on next Tuesday, Wednesday, or Thursday. I will follow up with potential times as soon as I hear back on availability, but please let me know if those dates are already not workable for your team.

Thank you,
Anthony Lee

Anthony Lee, PhD, MBA
Team Lead

Robotic Assisted Surgery Devices Team
Division of Health Technology 4A | OHT4: Surgical & Infection Control Devices
Office of Product Evaluation and Quality | Center for Devices and Radiological Health

U.S. FOOD & DRUG ADMINISTRATION

Office: (240) 402-5935
E-mail: Anthony.Lee1@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1611&S=E

From: Chris G <chris@rebotixrepair.com>
Sent: Monday, May 2, 2022 2:31 PM
To: Lee, Anthony <Anthony.Lee1@fda.hhs.gov>; Bittleman, Katelyn <Katelyn.Bittleman@fda.hhs.gov>

Cc: Rick Lyon <rick@dovel.com>; Glenn P <glennpapit@rebotixrepair.com>
Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

Thank you.

From: Lee, Anthony <Anthony.Lee1@fda.hhs.gov>
Sent: Monday, May 2, 2022 2:29 PM
To: Chris G <chris@rebotixrepair.com>; Bittleman, Katelyn <Katelyn.Bittleman@fda.hhs.gov>
Cc: Rick Lyon <rick@dovel.com>; Glenn P <glennpapit@rebotixrepair.com>
Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

Dear Mr. Gibson,
Yes, the date and time are confirmed on our end (this Friday at 10AM Eastern). I will send over the meeting invitation soon.

Thank you,

Anthony Lee, PhD, MBA
Team Lead

Robotic Assisted Surgery Devices Team
Division of Health Technology 4A | OHT4: Surgical & Infection Control Devices
Office of Product Evaluation and Quality | Center for Devices and Radiological Health

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Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?ID=1611&S=E

From: Chris G <chris@rebotixrepair.com>
Sent: Monday, May 2, 2022 2:26 PM
To: Lee, Anthony <Anthony.Lee1@fda.hhs.gov>; Bittleman, Katelyn <Katelyn.Bittleman@fda.hhs.gov>

Cc: Rick Lyon <rick@dovel.com>; Glenn P <glennpapit@rebotixrepair.com>
Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

Dear Dr. Lee,
Will you please confirm this zoom call? Thank you.

Sincerely,

Chris Gibson
Chief Operations Officer
Rebotix™ your prescription for savings
539 Pasadena Avenue South
St. Petersburg, FL 33707
P: (727) 345-6362
F: (727) 343-4637
C: (813) 245-3974
www.rebotixrepair.com

From: Chris G
Sent: Thursday, April 28, 2022 1:35 PM
To: Lee, Anthony <Anthony.Lee1@fda.hhs.gov>; Bittleman, Katelyn <Katelyn.Bittleman@fda.hhs.gov>
Cc: Rick Lyon <rick@dovel.com>; Glenn P <glennpapit@rebotixrepair.com>
Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

Dear Dr. Lee,
Friday May 6th, at 10 am EDT is perfect for us. Please send us the zoom call invite. Thank you.

Sincerely,

Chris Gibson
Chief Operations Officer

539 Pasadena Avenue South
St. Petersburg, FL 33707
P: (727) 345-6362
F: (727) 343-4637
C: (813) 245-3974
www.rebotixrepair.com

From: Lee, Anthony <Anthony.Lee1@fda.hhs.gov>
Sent: Thursday, April 28, 2022 12:58 PM
To: Chris G <chris@rebotixrepair.com>; Bittleman, Katelyn <Katelyn.Bittleman@fda.hhs.gov>
Cc: Rick Lyon <rick@dovel.com>; Glenn P <glennpapit@rebotixrepair.com>
Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

Dear Mr. Gibson,
May 2 and 3 conflict with our schedules. I would like to propose any of the following alternatives:

Thursday May 5: 11AM or 3PM EDT
Friday May 6: 10AM EDT

If none of these times work, please let me know.

Thank you,
Anthony

Anthony Lee, PhD, MBA
Team Lead

Robotic Assisted Surgery Devices Team
Division of Health Technology 4A | OHT4: Surgical & Infection Control Devices
Office of Product Evaluation and Quality | Center for Devices and Radiological Health
U.S. FOOD & DRUG ADMINISTRATION

Office: (240) 402-5935
E-mail: Anthony.Lee1@fda.hhs.gov

From: Chris G <chris@rebotixrepair.com>
Sent: Monday, April 25, 2022 12:36 PM
To: Lee, Anthony <Anthony.Lee1@fda.hhs.gov>; Bittleman, Katelyn <Katelyn.Bittleman@fda.hhs.gov>
Cc: Rick Lyon <rick@dovel.com>; Glenn P <glennpapit@rebotixrepair.com>
Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

Dear Dr. Lee & Dr. Bittleman.

We are a 3rd. party service provider consistent with the FDA's definition, and all of our repair business aligns with such. We service instruments in continuous hospital ownership and do not affect the effectiveness or the intended use of these instruments.

During our Zoom call you mentioned that our service was a "complicated" and "murky area" for FDA oversight, yet we have been more than open about our service process. On Feb. 28, 2020 the FDA reached out to us regarding our process. We immediately cooperated by providing all requested information via a succession of informative emails. We provided ample evidence of proper due diligence (formal risk management and design under 13485; service process performed under 9001; hospital/customer due diligence), and that our process returns the instrument to its safe operating condition.

In June of 2019 Dr. Bittleman visited our booth at the AAMI show in Cleveland at which time she was able to examine all aspects of our repair process, and ask any pertinent questions. She expressed no safety or other issues that would concern the FDA during that meeting.

Since the FDA's original contact we heard nothing back from the FDA for a year and nine months, which from our understanding, would indicate that the FDA was satisfied with our responses and the matter was closed. Despite the fact there has been no change in our process, or any known safety issues or customer complaints, on Nov. 16, 2021 we received an overnight delivery indicating the FDA was reopening the investigation. Then on April 8, 2022 we were advised of the FDA's determination that our process constituted remanufacturing.
If, as being suggested, there is an actual issue of patient safety, why has the FDA waited two and a half years to seek correction? By taking this action the FDA is effectively shuttering a small business that is positively affecting the costs of surgery budgets across the country. The question is why?

Following our Zoom call we requested follow up discussion. The FDA declined, choosing instead to direct us to a Q-submission. Our understanding is that our only alternative at this point is to initiate a formal

review/appeal with the FDA. We respectfully request to discuss this matter again. Please respond and advise if you are available for a meeting or call next Monday May 2nd, or Tuesday May 3rd. Thank you.

Sincerely,

Chris Gibson
Chief Operations Officer
Rebotix™ your prescription for savings
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St. Petersburg, FL 33707
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F: (727) 343-4637
C: (813) 245-3974
www.rebotixrepair.com

From: Lee, Anthony <Anthony.Lee1@fda.hhs.gov>
Sent: Friday, April 22, 2022 12:09 PM
To: Chris G <chris@rebotixrepair.com>
Cc: Rick Lyon <rick@dovel.com>
Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

Dear Mr. Gibson,
We would like to have a brief phone call to discuss the timeline and next steps. Proposed times are (all Eastern time):
4/25 at 2PM or 2:30PM
4/26 at 1:30PM or 2:30PM

If none of these times work, please let me know.

Thanks,

Anthony Lee, PhD, MBA
Team Lead

Robotic Assisted Surgery Devices Team
Division of Health Technology 4A | OHT4: Surgical & Infection Control Devices
Office of Product Evaluation and Quality | Center for Devices and Radiological Health

Office: (240) 402-5935
E-mail: Anthony.Lee1@fda.hhs.gov
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https://www.research.net/s/cdrhcustomerservice?ID=1611&S=E

From: Lee, Anthony
Sent: Tuesday, April 19, 2022 4:09 PM
To: Chris G <chris@rebotixrepair.com>
Cc: Rick Lyon <rick@dovel.com>; Bittleman, Katelyn <Katelyn.Bittleman@fda.hhs.gov>
Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

Dear Mr. Gibson,
Management has requested that you submit a Q-submission as previously described. This will allow your company to have a full documentation of items that were reviewed along with an official FDA written response, teleconference (if desired), and meeting minutes (if applicable). Please let me know if you have any questions about the process.

Thank you,
Anthony Lee

Anthony Lee, PhD, MBA
Team Lead

Robotic Assisted Surgery Devices Team
Division of Health Technology 4A | OHT4: Surgical & Infection Control Devices
Office of Product Evaluation and Quality | Center for Devices and Radiological Health

Office: (240) 402-5935
E-mail: Anthony.Lee1@fda.hhs.gov

From: Chris G <chris@rebotixrepair.com>
Sent: Friday, April 15, 2022 3:13 PM
To: Lee, Anthony <Anthony.Lee1@fda.hhs.gov>
Cc: Rick Lyon <rick@dovel.com>; Bittleman, Katelyn <Katelyn.Bittleman@fda.hhs.gov>
Subject: Re: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

Dr. Lee,
Thank you for the quick response, we would very much appreciate a meeting the week of 4/25. Thank you.

Sincerely,

Chris Gibson

> On Apr 15, 2022, at 2:55 PM, Lee, Anthony <Anthony.Lee1@fda.hhs.gov> wrote:
>
> Sending a quick followup. I'm checking with management to see if we can fast-track a meeting with your proposed week. If that won't work, then the previously-mentioned Q-submission will be the proper approach. I'll send another followup on Monday to confirm.
>
> Thanks,
> Anthony

Anthony Lee, PhD, MBA
Team Lead

Robotic Assisted Surgery Devices Team
Division of Health Technology 4A | OHT4: Surgical & Infection Control Devices
Office of Product Evaluation and Quality | Center for Devices and Radiological Health

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E-mail: Anthony.Lee1@fda.hhs.gov
Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?ID=1611&S=E

From: Lee, Anthony
Sent: Friday, April 15, 2022 10:34 AM
To: Chris G <chris@rebotixrepair.com>; Rick Lyon <rick@dovel.com>
Cc: Bittleman, Katelyn <Katelyn.Bittleman@fda.hhs.gov>
Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

Mr. Gibson,
Thank you for following up. I was on leave until yesterday and have been catching up with my messages. We are open to additional discussion, however this should occur through the formal Q-submission process. With your submission, you can provide information for the FDA team to review along with any questions in which you would like a formal response.

If you wish to proceed with a Q-submission, please confirm and we will stand by for your submission. Due to the ongoing pandemic, FDA is not currently open to in-person meetings, however teleconferences are still acceptable.

Thanks,
Anthony

Anthony Lee, PhD, MBA
Team Lead

Robotic Assisted Surgery Devices Team
Division of Health Technology 4A | OHT4: Surgical & Infection Control Devices
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https://www.research.net/s/cdrhcustomerservice?ID=1611&S=E

From: Chris G <chris@rebotixrepair.com>
Sent: Friday, April 15, 2022 9:16 AM
To: Lee, Anthony <Anthony.Lee1@fda.hhs.gov>; Rick Lyon <rick@dovel.com>
Cc: Bittleman, Katelyn <Katelyn.Bittleman@fda.hhs.gov>
Subject: Re: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

Dr. Lee and Dr. Bittleman,
We are requesting confirmation that you have received our email dated 4/11 and that we have requested an in-person meeting for the week of 4/25. Please confirm, thank you.

Sincerely,

Chris Gibson

> On Apr 11, 2022, at 11:14 AM, Chris G <chris@rebotixrepair.com> wrote:
>
> Dear Dr. Lee and Dr. Bittleman,
>
> Thank you for your time and consideration. We appreciate your acknowledgment on the call that whether a process constitutes remanufacturing is a "murky area" under the current FDA guidelines and that new guidelines are forthcoming. We also appreciate your explanation of our options going forward: whether to pursue FDA clearance (e.g., a 510(k)) or to provide Objections to your decision so that the FDA can further consider the issue as it works to finalize its guidelines. To this end we wish to request an in person meeting at your offices to begin the collaborative assistance you offered on our zoom call. Please let us know if you have availability the week of April 25th.
>
> Best regards,
>
> Chris Gibson

From: Lee, Anthony <Anthony.Lee1@fda.hhs.gov>
Sent: Friday, April 8, 2022 2:28 PM
To: Rick Lyon <rick@dovel.com>; Chris G <chris@rebotixrepair.com>

Cc: Bittleman, Katelyn <Katelyn.Bittleman@fda.hhs.gov>
Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

Dear Rick and Chris,
Thank you for your time earlier today. As mentioned during our call, the Agency believes that the activities of Rebotix constitute remanufacturing and would require FDA review and clearance (e.g. 510(k) / de Novo). We therefore request that Rebotix stop engaging in the current activities until an application is reviewed and cleared/granted.

The instruments in question no longer maintain the same safety and effectiveness profile as cleared with the original manufacturer's own submission. During premarket review, FDA reviews test data to the labeled number of reuse cycles. This includes, but is not limited to, items such as electrical safety, reprocessing, software, and general performance testing. By extending the number of uses and modifying the instrument with a new chip, the prior information is no longer valid and requires additional review to the new labeled usage limit in order to establish safety and effectiveness. This is therefore different than returning the device to its original condition.

Please let us know if you have any further questions and what your intentions are for next steps.

Thank you again,
Anthony

Anthony Lee, PhD, MBA
Team Lead

Robotic Assisted Surgery Devices Team
Division of Health Technology 4A | OHT4: Surgical & Infection Control Devices
Office of Product Evaluation and Quality | Center for Devices and Radiological Health
U.S. FOOD & DRUG ADMINISTRATION

Office: (240) 402-5935
E-mail: Anthony.Lee1@fda.hhs.gov
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From: Rick Lyon <rick@dovel.com>
Sent: Wednesday, April 6, 2022 1:13 PM
To: Lee, Anthony <Anthony.Lee1@fda.hhs.gov>

Cc: Chris G <chris@rebotixrepair.com>
Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

Thank you, Anthony. 1 PM ET works for us. What is the best number to reach you? Or if you prefer, I can send call-in information.

Thanks,
Rick

From: Lee, Anthony <Anthony.Lee1@fda.hhs.gov>
Sent: Wednesday, April 06, 2022 5:58 AM
To: Rick Lyon <rick@dovel.com>
Cc: Chris G <chris@rebotixrepair.com>
Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

Dear Rick,
A decision has been made regarding CPT2000126 and Rebotix Repair. We would like to request a short teleconference. Are you and someone from Rebotix available to discuss this Friday at 1PM ET?

Thanks,
Anthony

Anthony Lee, PhD, MBA
Team Lead

Robotic Assisted Surgery Devices Team
Division of Health Technology 4A | OHT4: Surgical & Infection Control Devices
Office of Product Evaluation and Quality | Center for Devices and Radiological Health

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From: Lee, Anthony
Sent: Monday, December 13, 2021 10:56 AM
To: Rick Lyon <rick@dovel.com>
Cc: Chris G <chris@rebotixrepair.com>
Subject: RE: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

Good morning Rick,
We have discussed your request internally, and we are ok with extending the response by an additional 30 days. We look forward to hearing back from you in January.

Regards,
Anthony

Anthony Lee, PhD, MBA
Team Lead

Robotic Assisted Surgery Devices Team
Division of Health Technology 4A | OHT4: Surgical & Infection Control Devices
Office of Product Evaluation and Quality | Center for Devices and Radiological Health

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From: Rick Lyon <rick@dovel.com>
Sent: Friday, December 10, 2021 11:51 AM
To: Lee, Anthony <Anthony.Lee1@fda.hhs.gov>
Cc: Chris G <chris@rebotixrepair.com>
Subject: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126

Dear Dr. Lee,

Thank you for taking the time to speak with me. Following up on our conversation, would it be possible to extend the deadline for our submission of the information you requested by 30 days? This would make the information due January 15, 2022, instead of next Thursday (December 16, 2021).

Best regards,
Rick Lyon
310-656-7066
Counsel for Rebotix Repair LLC